



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project “*Ambulatory Surgery Center Survey on Patient Safety Culture Database*.” This proposed information collection was previously published in the Federal Register on May 25, 2021 and allowed 60 days for public comment. AHRQ did not receive substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting

"Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Ambulatory Surgery Center Survey on Patient Safety Culture Database

Ambulatory surgery centers (ASCs) are a fast-growing healthcare setting, demonstrating tremendous growth both in the volume and complexity of procedures being performed. ASCs provide surgical services to patients who are not expected to need an inpatient stay following surgery. The Centers for Medicare and Medicaid Services (CMS) defines ASCs as distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to stay in a surgical facility longer than 24 hours.

AHRQ's mission. As described in its 1999 reauthorizing legislation, Congress directed the Agency for Healthcare Research and Quality (AHRQ) to enhance the quality, appropriateness, and effectiveness of health services, as well as access to such services, by establishing a broad base of scientific research and promoting clinical and health systems practice improvements. The legislation also directed AHRQ to "conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to health statistics, surveys, database development, and epidemiology."

Furthermore, AHRQ shall conduct and support research "to provide objective clinical information to health care practitioners and other providers of health care goods or services; identify the causes of preventable health care errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the health care industry".

Background on the Ambulatory Surgery Center Survey on Patient Safety Culture (ASC SOPS). In 1999, the Institute of Medicine called for health care organizations to develop a "culture of safety" such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health System). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot

tested the ASC Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0216; approved October 31, 2013).

The survey is designed to enable ASCs to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 27 items that measure 8 composites of patient safety culture. In addition to the composite items, the survey includes one item measuring how often ASCs document near-misses; one item asking whether the respondent is in the room during surgeries, procedures, or treatments; and three items about communication before and after surgeries, procedures, or treatments. The survey also includes an overall rating item on patient safety, two items about respondent characteristics, and a section for open-ended comments. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in May 2015 on the AHRQ website.

The AHRQ ASC SOPS Database consists of data from the AHRQ ASC Survey on Patient Safety Culture. Ambulatory surgery centers in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The ASC SOPS Database (OMB NO. 0935-0242; Approved September 10, 2018) was developed by AHRQ in 2019 in response to requests from ASCs interested in tracking their own survey results. Organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other ASCs submitting data. These reports are used to assist ASC staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The ASC SOPS and the ASC SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care in ASCs. The survey, toolkit materials, and database results are all made publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to ASCs, to facilitate the use of these materials for ASC patient safety and quality improvement.

Rationale for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ ASC SOPS Database; OMB NO. 0935-0242; Approved September 10, 2018.

This database will:

1. Present results from ASCs that voluntarily submit their data;
2. Provide data to ASCs to facilitate internal assessment and learning in the patient safety improvement process; and
3. Provide supplemental information to help ASCs identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to health statistics, surveys, and database development.. 42 U.S.C 299a(a)(1) and (8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

1. Eligibility and Registration Form -- The point-of-contact (POC), often the manager of the ASC, completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the ASC and initiate the registration process.

2. Data Use Agreement – The purpose of the data use agreement, completed by the ASC manager, is to state how data submitted by ASCs will be used and provides privacy assurances.
3. ASC Site Information– The purpose of the site level specifications, completed by the ASC POC, is to collect background characteristics of the ASC. This information will be used to analyze data collected with the ASC SOPS survey.
4. Data Files Submission –POCs upload their data file(s), using ASC survey data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because ASCs do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an ASC administrative manager or a survey vendor who contracts with an ASC to collect and submit its data.

Survey data from the AHRQ Ambulatory Surgery Center Survey on Patient Safety Culture are used to produce three types of products:

- 1) An ASC SOPS Database Report that will be made publicly available on the AHRQ website (see ASC Database Report);
- 2) Individual ASC Survey Feedback Reports that are customized for each ASC that submits data to the database; and
- 3) Research data sets of individual-level and ASC-level de-identified data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual-level and the ASC-level.

ASCs will be invited to voluntarily submit their ASC SOPS survey data into the database.

AHRQ's contractor, Westat, then cleans and aggregates the data to produce a PDF-formatted Database Report displaying averages, standard deviations, and percentile scores on the survey's items and patient safety culture composite measures. The report also displays these results by

ASC characteristics (e.g., number of operating/procedure rooms and geographic region) and respondent characteristics (e.g., staff position and hours worked per week).

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. ASC population. Because participating ASCs will choose to voluntarily submit their data into the database and therefore are not a random or national sample of ASCs, estimates based on this self-selected group might be biased estimates. We recommend that users review the database results with these caveats in mind.

Each ASC that submits its data receives a customized survey feedback report that presents their results alongside the aggregated results from other participating ASCs.

ASCs use the ASC SOPS Survey, Database Reports, and Individual ASC Survey Feedback Reports for a number of purposes, to:

- Raise staff awareness about patient safety;
- Elucidate and assess the current status of patient safety culture in their ASC;
- Identify strengths and areas for patient safety culture improvement;
- Examine trends in patient safety culture change over time; and
- Evaluate the cultural impact of patient safety initiatives and interventions.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 100 ASC managers (i.e., POCs from ASCs) will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 5 minutes).
- Data use agreement (completion is estimated to take about 3 minutes).

- ASC Site Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total burden is estimated to be 121 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$5,804.37

Exhibit 1. Estimated annualized burden hours

Form Name	Number of Respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility and Registration Form	100	1	5/60	8
Data Use Agreement	100	1	3/60	5
ASC Site Information Form	100	1	5/60	8
Data Files Submission	100	1	1	100
Total	NA	NA	NA	121

Exhibit 2. Estimated annualized cost burden

Form Name	Number of Respondents/POCs	Total burden hours	Average hourly wage rate*	Total cost burden
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Eligibility and Registration Form	100	8	\$47.97	\$383.76
Data Use Agreement	100	5	\$47.97	\$239.85
ASC Site Information	100	8	\$47.97	\$383.76
Data Files Submission				\$4,797.0
	100	100	\$47.97	0
Total				\$5,804.3
	NA	121	NA	7

*Based on the mean hourly wage for 100 ASC Administrative Services Managers (11-3010; \$47.97) obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 621400 – Outpatient Care Centers (located at https://www.bls.gov/oes/current/naics4_621400.htm#11-00000).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 25, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021-18694 Filed: 8/30/2021 8:45 am; Publication Date: 8/31/2021]